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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/518,940   | 06/08/2005  | Yufen Zhao           | 15431.4             | 3531             |
| 22913  | 7590        | 11/21/2005           | EXAMINER            |                  |
| WORKMAN NYDEGGER<br>(F/K/A WORKMAN NYDEGGER & SEELEY)<br>60 EAST SOUTH TEMPLE<br>1000 EAGLE GATE TOWER<br>SALT LAKE CITY, UT 84111 |             |                      | SHIRALI, SHYAM S    |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 1654                 |                     |                  |
| DATE MAILED: 11/21/2005  |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                           |                  |
|------------------------------|---------------------------|------------------|
| <b>Office Action Summary</b> | Application No.           | Applicant(s)     |
|                              | 10/518,940                | ZHAO ET AL.      |
|                              | Examiner<br>Shyam Shirali | Art Unit<br>1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

1. Claim 10 - 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The examiner has contacted the attorney for the following issues which are not clear.

Claim 15, 16 is objected for spelling. It should be "petroleum ether" and not "petrolium ether".

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 -24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically: because of the following reasons.

4. Claims 10, 11 are indefinite in their use of the symbol " ~ ". This symbol is frequently used to mean "approximately". It is not clear whether "0 ~ 4" for example, is intended to mean a range of 0 to 4, or something else.

In the claim 11, the final product Alanylglutamine is obtained by acidification of reaction mixture of step 2 to pH 2.0- 3.0. but in claim 10 the final product is obtained by the reaction of deprotecting agent with the N-protected alanylglutamine. And therefore it is

not very clear that the step of deprotection using deprotecting reagent is a essential or acidic conditions are enough to get the final product (deprotected product).

Claims 15,16 recites the list of organic solvents and one of them is "ethanol ethyl acetate", being ethanol and ethyl acetate different solvents they should be separated by a coma after ethanol. Which makes "ethanol", "ethyl acetate".

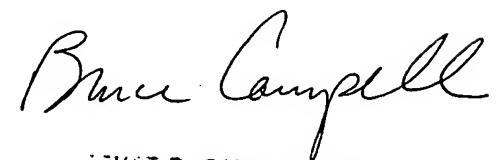
Claims 21, 22 are indefinite they recites the deprotection of the N-protected alanylglutamine by hydrogenation. It is a deprotection reaction by using nescient hydrogen in the presence of catalyst and not a reagent like other listed in the claims.

Conclusion:

No claim is allowed. However, all the claims are free of prior art because the reaction conditions, reagents and solvents are new in this reaction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shyam Shirali whose telephone number is (571)-272-5547. The examiner can normally be reached on 8.00am to 4.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Bruce Campell can be reached on (571) 272- 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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